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CLINICAL INVESTIGATION STROKE

Efficacy of Mechanical Thrombectomy Using Stent Retriever and Balloon-Guiding Catheter

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Abstract
Purpose Intra-arterial therapy of acute ischemic stroke has developed rapidly in recent years. Due to proven efficacy in randomized trials, stent retrievers were replacing first-generation thrombectomy devices and have been defined as method of choice. However, aspiration catheters or a combination of several techniques have shown promising rates of successful recanalizations. To create a basis for comparison of the new approaches according to real-world data, we determined the first pass recanalization rate of an evidence-based standard technique with the use of a stent retriever in combination with a balloon-guiding catheter. The assessment was based on the number of required passages and reperfusion rate, but not on clinical results.
Methods Patients from our institution with anterior circulation occlusions and mechanical thrombectomy by using stent retrievers in combination with balloon-guiding catheters were analyzed retrospectively. Reperfusion was graded with the "thrombolysis in cerebral infarction" (TICI) classification on post-interventional angiograms. Additionally, the number of passes and the duration of the recanalization procedure were recorded.
Results Between 2014 and July 2017, 201 patients met the inclusion criteria. Successful recanalization, defined as a TICI scale 2b/3, was 91% (TICI 2b was achieved in 44% and TICI 3 in 47%) after the procedure. After the first passage, successful recanalization was achieved in 65% of the patients. Mean number of passes was 1.4 (1–5 passes) for all patients. Median duration of the procedure was 49 min (0:11–2:35 h).
Conclusions Even a standard thrombectomy technique with the use of a stent retriever together with a balloon-guiding catheter provides reasonable recanalization rates with only one passage. The results can be taken as benchmark for alternative and more complex techniques.

Keywords Stroke · Acute · Endovascular therapy · Thrombectomy · Stent retriever thrombectomy

Introduction

After thrombolysis was considered as standard therapy for several decades [1], treatment of large vessel occlusions changed markedly with the publication of five positive randomized studies predominantly using stent retrievers [2–6]. These studies have led to highest level guideline recommendations [7–9] toward thrombectomy within 6 h of onset of ischemic stroke due to large vessel occlusion in the anterior circulation [10]. The most common devices in the pivotal trials, Solitaire stent retriever (Medtronic, Dublin, Ireland) and Trevo stent retriever (Stryker, Kalamazoo, Michigan, USA), [10–12], are still considered to be the current standard, but recently were supplemented by new approaches using aspiration catheters or combinations between aspiration catheters and stent retrievers [13–16].

Balloon-guiding catheters (BGC) had already been introduced together with first-generation thrombectomy devices to prevent peripheral embolism by temporary flow arrest during the retrieval maneuver. Distal access catheters

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placed as close as possible to the thrombectomy site should also prevent embolism into other vessel territories [10]. The development of large-bore flexible aspiration catheters enabled direct thrombus aspiration without passage and deployment of a stent retriever. Lapergue et al. [15] stated that "A direct aspiration first pass technique" for the endovascular treatment of stroke (ADAPT) shows higher rates of recanalization, compared to stent retrievers. Alternatively the "SOLUMBRA technique," which means to place a large-bore aspiration catheter immediately adjacent to the deployed stent retriever and remove the stent retriever into the catheter under aspiration should minimize the chance of fragmentation [17–20]. Maus et al. reported the "SAVE technique" (stent retriever-assisted vacuum-locked extraction) to be a very fast and effective technique with complete reperfusion rates (TICI III) of 72% of the patients. A stent retriever is deployed across the thrombus, which is retrieved into the entrance of an aspiration catheter until arrest of the backflow of continuous aspiration. Then the aspiration catheter with the locked stent retriever is retrieved under aspiration of the guiding catheter [21].

Currently, the value and efficacy of the new techniques are under investigation, which among others has led to concerns that with widespread use of thrombectomy centers could deviate from the use of evidence-based techniques.

Thus, our study aimed to retrospectively assess the efficacy of a well-established technique of retriever-assisted thrombectomy in combination with BGCs for recanalization of anterior circulation occlusions in a real-world setting of a single academic center with several staff members in training for interventional stroke treatment. We focused on the recanalization rate and time between groin puncture and successful recanalization to get an idea of what we can achieve with a relatively simple and evidence-based standard technique as a benchmark for evaluation of more alternative recanalization strategies. The success of the recanalization was determined by the reperfusion score and not by clinical results.

Materials and Methods

Study Population

This retrospective descriptive review was approved by the institutional review board. We performed a retrospective analysis of patients with anterior circulation ischemic strokes who were admitted to our stroke unit and received mechanical thrombectomy due to large cerebral artery occlusion. Patient data were obtained from the electronic medical records.

Three hundred and seventeen patients were treated by mechanical recanalization between January 2014 and July 2017 in our institution; of these 170 patients with vessel occlusions including posterior circulation were treated with stent retriever. Of these, in turn 140 fulfilled the inclusion criteria, meaning that they were treated by stent retriever in combination with BGC due to anterior circulation occlusion. Since BGCs are not used in the posterior circulation, patients with vessel occlusions of the basilar artery or vertebral arteries were excluded. Also, patients with tandem occlusions comprising a preceding extracranial occlusion or stenosis and those who received mechanical thrombectomy using different devices, e.g., aspiration catheters were not included in our study. Patients with atherothrombotic occlusions due to intracranial stenosis were excluded as well. In 15 patients, BGCs could not be placed due to angulation or tortuosity of the carotid bifurcation of cervical segment of the internal carotid artery. In 22 cases with tandem occlusions and necessity of acute carotid stenting, we did not use BGCs because the 5F inner lumen was not compatible with some of the carotid stent types used.

Our database includes demographic characteristics, times of beginning and ending of the intervention resulting in the duration of the intervention, and the number of passes needed. Precisely, our subgroup analysis contained 75 male and 95 female patients, and mean age was 71 years. The site of intracranial vascular occlusion was differentiated into the main branches of the anterior circulation (internal carotid artery, carotid-T, and M1 or dominant M2-branch of the middle cerebral artery, anterior cerebral artery). The cause of the vessel occlusion was embolic in all cases. Reperfusion of the primary large cerebral artery occlusion was graded with the "Thrombolysis In Cerebral Infarction (TICI) scale" [22, 23]. Successful recanalization was defined as TICI 2b or 3.

Treatment Protocol

To place the stent retriever at the site of the vessel occlusion, a balloon-guiding catheter (Cello 8F, Medtronic Neurovascular, Irvine, CA, USA) was placed into the internal carotid artery. The site of thrombus was passed with a microwire and microcatheter. A Solitaire stent retriever (Medtronic Neurovascular, Irvine, CA, USA) was deployed across the thrombus. In the rare instances of long thrombi or peripheral second-order branch occlusion the Aperio (Acandis Pforzheim, Germany) stent retriever was preferably used. After a waiting period of 5–6 min, the stent retriever was pulled back under temporary balloon occlusion and aspiration at the guiding catheter. In case of insufficient success, the procedure was repeated up to three times. In case of unsuccessful recanalization with the

Solitaire, the Trevo (Stryker Neurovascular, Kalamazoo, MI, USA) or aspiration catheters (SOFIA 5 and 6F, Microvention, Tustin, CA 92780 USA and 3-/5-/6-Max-catheters, Penumbra, Alameda, CA, USA) were tried as secondary devices. Thirteen patients requiring the use of aspiration catheters as part of such a rescue protocol were excluded from this analysis to avoid bias by different products or recanalization techniques. Unsuccessful recanalizations using different types of stent retrievers as secondary device, however, are part of the evaluation.

Data Sources/Assessment

Hospital electronic medical records (Orbis) and images from digital subtraction angiograms (DSA) from each case were assessed for the following data: date of birth, sex, site of thrombus, side of the occluded vessel, post-intervention TICI scales, time from beginning of the procedure to successful recanalization, procedures (stenting, angioplasty, stent retriever, and/or aspiration thrombectomy), device used for thrombectomy, and number of passes needed until recanalization was achieved. Statistical analysis was performed to calculate the frequencies of categorical variables and the mean for numerical variables with a special focus on the subgroup of patients treated with stent retriever only.

Results

Patient Characteristics

The series included 95 females and 75 males, treated with stent retriever + balloon-guiding catheters (BCG). The mean age of these patients was 71 years. A total of 118 patients had an occlusion of the MCA and 26 had an isolated ICA occlusion (Table 1). Eighty-four of the anterior circulation lesions were on the left side, whereas 60 presented on the right side (Table 1).

All procedures were performed under general anesthesia.

Angiographic Outcome

A post-procedural TICI scale of 2b/3 was achieved with stent retriever + BCG in 154 of 170 patients (91%); of these 74 patients were treated with a TICI scale 2b and 80 with TICI scale 3 (Table 2). The less-often used subcategory 2c (recanalization without any distal vessel occlusions, but with delay in contrast runoff [23]) was achieved in 14 out of 74 TICI 2b patients. The others had peripheral branch occlusions. TICI 2b/3 recanalization was achieved in 110 out of 170 patients (65%) with only one retrieval maneuver. Two passes were needed in 31 patients (20%). Thirteen patients (8%) needed three or more passes. Mean number of passes was 1.45 for patients treated TICI 2b and 1.28 for patients treated TICI 3. Less favorable TICI 2a was achieved in nine patients (5.3%), of which three needed one pass (1.8%) and six needed two passes (3.5%). Patients (4.1%) were treated TICI 0. In most of these cases, three or more passes were tried. (1.8% of all patients were treated with stent retriever + BCG only.) Details are displayed in Table 2. In one patient, the thrombus site could not be reached and the procedure had to be aborted without success. Mean number of passes was 1.67 for patients treated with TICI 2a and 2.43 for patients treated with TICI 0.

Median duration from groin puncture to recanalization was 49 min for all patients, 49 min for patients with TICI 2b and 40 min for patients with TICI 3 (Table 3). Regarding the subgroups, if only one passage was necessary, the median duration of the intervention was 42 min to accomplish TICI 2b and 36 min to achieve TICI 3. The duration of the procedure increased significantly with the increase in the number of necessary passages. In case two passages were necessary, the median duration of the intervention was 60 min for TICI 2b and 55 min to accomplish TICI 3. If three or more passes were necessary, TICI 2b was achieved within a median duration of 1:16 h and TICI 3 within 51 min (Table 3). For both a TICI 2a result and TICI 0, the median of the required time was 1:27 h.

Symptomatic intraparenchymal cerebral hemorrhages occurred in four patients (2.3%). Peripheral embolism requiring rescue thrombectomy with smaller stent retrievers occurred in two patients. Four further patients had embolism into small peripheral branches without further specific treatment.

Table 1 Number of patients per localization (anterior circulation only) of the vessel occlusion

Localization of the occlusion	ICAr	ICAl	MCAr	MCAl
Number of patients	10	16	50	68

Discussion

According to the results of several other study sites, our study shows that even with a use of an established and evidence-based standard technique, reasonable successful recanalization rates TICI 2b/3 of 91% in total and of 65% after the first pass could be achieved [24]. This corresponds well with data from the multicentered STRATIS registry with use of the same technique in a subgroup of 984

Table 2 Percentage of patients treated with the corresponding TICI scale depending on the number of passages

	Total	One pass	Two passes	Three or more passes	Mean number of passes
TICI 0	4.1%	0.6%	1.2%	1.8%	2.43
TICI 1	0	0	0	0	0
TICI 2a	5.3%	1.8	3.5%	0	1.67
TICI 2b	43.5%	28.8%	8.8%	5.9%	1.45
TICI 3	47.1%	35.9%	9.4%	1.8%	1.28

Table 3 Time (in hours:minutes) needed to achieve full recanalization (defined as TICI 2b-3) with the corresponding TICI scale depending on the number of passages

	Median time (hours:minutes)	Median time One pass	Median time Two passes	Median time Three passes	Total median time
TICI 0	1:27	1:00	2:05	1:27	0:49
TICI 1	0	0	0	0	
TICI 2a	1:27	1:45	1:14	0	
TICI 2b	0:49	0:42	1:00	1:116	
TICI 3	0:40	0:36	0:55	0:51	

patients treated at 55 sites [25]. STRATIS proved TICI 2b/3 rates of 87.9% achieved in an average time to reperfusion of 44 min. Our average procedural time of 49 min was only slightly higher probably due to the fact that less experienced operators in our team needed some more time than the senior interventionists.

Our recanalization rate is also within the range of angiographic outcomes reported in the five randomized controlled trials (RCTs) demonstrating mechanical thrombectomy to be superior to standard medical management alone [26–32].

Previously, several different stent retrievers have emerged over the past years. Data with higher levels of scientific evidence are mainly available for the Solitaire and Trevo stent retriever used in the RCTs, showing comparable results to our single-center study. For other stent retrievers with partly similar designs, only data from case series and registries are available showing similar recanalization rates as well [16, 33].

Recently, some new approaches were introduced as promising alternatives to stent retriever thrombectomy, such as ADAPT for pure thrombus aspiration or more complex techniques with combinations between aspiration catheters and stent retrievers like SOLUMBRA or SAVE [29, 34–37]. The SAVE authors tried to justify their complex technique with high rates of successful first pass recanalization rates of 72% (23 out of 32 patients) that resulted in mTICI 3 and 100% that resulted in successful reperfusion, defined asm-TICI $\geq$ 2b [21]. However, this study considers only a small number of participants [21]. Several trials described superior results of aspirations techniques by being substantially faster and achieving final successful aspiration rates of 80–90% [27–29, 31, 34, 36, 38]. In addition, some of the studies that use ADAPT promise the greater cost-effectiveness, compared to the use of stent retrievers [35, 38]. The randomized ASTER trial did not confirm the direct aspiration to be superior to the use of stent retrievers. TICI 2b/3 rates for both modalities were similar with 85.4% after aspiration and 83.1% after stent retrievers [24]. The rate of patients with a need for rescue therapies due to failure of primary approach was significantly higher in the direct aspiration group [24].

Before publication of ASTER, other studies dealing with primary aspiration showed that additional recanalization approaches are often supplemented with stent retrievers in the event of a lack of success. This leads to significantly lower recanalization rates exclusively achieved through aspiration catheters, between 28 and 76% [15, 29, 30, 35, 38, 39], compared to consistently reported recanalization rates with the use of Solitaire or Trevo stent retrievers of more than 80% [24, 40, 41]. As extension of this technique, the SOLUMBRA technique, in which the aspiration catheter is guided up to the clot by using the deployed stent retriever, is advocated. SOLUMBRA could be particularly helpful if the aspiration catheter cannot be placed directly adjacent to the clot [13, 14]. However, this technique has been reported to be associated with a higher risk of distal embolization and higher rates of symptomatic intracranial hemorrhage probably owing to endothelial damage [14, 20]. Besides that, the average number of stent retriever passes in the SOLUMBRA group was 2.1 and the average number of ADAPT passes was 2.5, resulting in a much greater time delay compared to the 1.45 and 1.28 passes required for stent retrievers to achieve successful recanalization (TICI 2b and 3).

The overall duration of the procedure did not differ significantly between the stent retriever technique in our

study group with mean durations between 37 and 57 min (49 min) and in the literature postulated durations of aspiration techniques (37–70 min) [17, 42–45]. At last, a certain risk of periprocedural complications, e.g., bleedings, vessel ruptures, contrast media extravasations, or formation of pseudoaneurysm after aspiration thrombectomy, are controversially debated in the literature. While Prothmann et al. or Kabbasch et al. did not observe any complications during use of aspirations technique only, several studies report higher rates of aspiration catheters, compared to stent retriever techniques, leading to unfavorable outcome deteriorations [30, 35, 43, 44, 46, 47]. Additionally, the risk of periprocedural embolization to initially uninvolved vascular territories when using aspiration catheters is contributing to an unfavorable clinical outcome [29]. In such a case, carryover of blood clots could still be treated by using smaller stent retrievers.

Similar to the data from the STRATIS registry [25], a recently published meta-analysis showed that the use of BGCs proves significantly better recanalization rates [48]. According to these data, retrieval of stent retrievers into BGCs is significantly more effective than the use of guiding catheters without balloon, distal access, or aspiration catheters.

The preparation and placement of BGCs are regarded as difficult and time consuming by some people. Since our team members decided to use BGC as standard, access device placement was successful in 131 of the 144 cases. Proximal flow arrest prevents embolism in new territories, especially in soft elastic clots [20, 38]. Recent evaluations combined BGCs and aspiration techniques (two-stage aspiration technique) to reduce embolization to new territories, but prolonging the duration of the procedure and leading to new challenges like arresting the BGC at the proximal portion in order not to cause vessel injuries [27].

With a low rate of peripheral embolism of 0.6% and SICH of 2.4%, our preferred technique proved favorable safety data. Local complications like dissection at the site of balloon inflation were rare. Vasospasm occurred occasionally and resolved spontaneously at the end of the procedure after removal of the access system.

Limitations

The value of this evaluation is limited by the retrospective and monocentric approach of data collection and analysis, although few study groups that have investigated the same questioning came to the same conclusion [19]. Additionally, the self-reported TICI scales have slight variabilities between the raters compared to core laboratory evaluation. A bias toward favorable cases may also play a role due to the fact that alternative techniques with the use of direct aspiration were mainly used in cases with extreme tortuosities.

Conclusions

Mechanical thrombectomy using stent retriever in combination with BGCs achieves reasonable overall and first pass recanalization rates.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval For this type of study formal consent is not required.

Informed Consent Written informed consent was waived by the institutional review board.

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